

# COVID-19 Moderna Vaccine Analysis Print

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All UK spontaneous reports received up to and including 15/12/21 for COVID-19 Moderna vaccine analysis print

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## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Iron deficiency anaemia	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	3	0
<i><b>Anaemias haemolytic NEC</b></i>		
Haemolytic anaemia	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	3	0
Spontaneous haematoma	1	0
<i><b>Coagulopathies</b></i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i><b>Haematological disorders</b></i>		
Blood disorder	1	0
Mast cell activation syndrome	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	180	0
Lymphadenitis	14	0
Lymphadenopathy	986	0
<i><b>Neutropenias</b></i>		
Autoimmune neutropenia	1	0
Neutropenia	2	0
<i><b>Sickle cell trait and disorders</b></i>		
Sickle cell anaemia with crisis	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	5	0
Thrombocytopenia	20	0
Thrombocytopenic purpura	1	0
<b>Blood disorders SOC TOTAL</b>	<b>1223</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	1	0
Bundle branch block left	1	0
Bundle branch block right	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	6	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	2	0
Palpitations	604	0
<i><b>Cardiomyopathies</b></i>		
Congestive cardiomyopathy	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	2	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	1	0
Angina pectoris	26	0
Myocardial infarction	10	0
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	2	0
Left ventricular dysfunction	2	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
<i><b>Noninfectious myocarditis</b></i>		
Hypersensitivity myocarditis	1	0
Myocarditis	106	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	62	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	16	0
Bradycardia	9	0
Cardiac fibrillation	1	0
Cardiac flutter	55	0
Extrasystoles	22	0
Tachycardia	160	0
Tachycardia foetal	1	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	10	0
Atrial flutter	5	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	2	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	2	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	4	0

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b> Cardiac disorders cont'd		
Ventricular extrasystoles	1	0
Ventricular tachycardia	3	0
<b>Cardiac disorders SOC TOTAL</b>	<b>1130</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	2	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	6	0
Ear discomfort	3	0
Ear disorder	2	0
Ear inflammation	1	0
Ear pain	145	0
Ear swelling	3	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube obstruction	1	0
<i><b>External ear disorders NEC</b></i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i><b>Hearing losses</b></i>		
Deafness	21	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	20	0
Sudden hearing loss	9	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	5	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	1	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	13	0
Tinnitus	211	0
Vertigo	171	0
Vertigo labyrinthine	1	0
Vertigo positional	8	0
<b>Ear disorders SOC TOTAL</b>	<b>630</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	6	0
Ovulation delayed	9	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	4	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
<b>Endocrine disorders SOC TOTAL</b>	<b>31</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	2	0
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Chorioretinopathy	1	0
Vitreous floaters	8	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	4	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	20	0
Eyelid ptosis	2	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Uveitis	4	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	20	0
Lacrimation increased	6	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Eyelid rash	1	0
Swelling of eyelid	10	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haematoma	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	2	0
Eye pain	169	0
Eye swelling	59	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	2	0
Periorbital swelling	10	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	2	0
Eye discharge	1	0
Eye inflammation	2	0
Eye irritation	12	0
Eye pruritus	19	0
Ocular hyperaemia	20	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	5	0
<i><b>Ocular sensation disorders</b></i>		
Abnormal sensation in eye	1	0
Asthenopia	10	0
Foreign body sensation in eyes	4	0
Hypoaesthesia eye	3	0
Photophobia	75	0
<i><b>Optic disc abnormalities NEC</b></i>		
Optic discs blurred	1	0
Papilloedema	1	0
<i><b>Optic nerve bleeding and vascular disorders</b></i>		
Optic ischaemic neuropathy	1	0
<i><b>Orbital infections, inflammations and irritations</b></i>		
Orbital myositis	1	0
<i><b>Pupil disorders</b></i>		



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<b>Eye disorders</b> Eye disorders cont'd		
Mydriasis	3	0
<b><i>Refractive and accommodative disorders</i></b>		
Accommodation disorder	1	0
Astigmatism	2	0
<b><i>Retinal bleeding and vascular disorders (excl retinopathy)</i></b>		
Retinal haemorrhage	1	0
Retinal vein occlusion	3	0
<b><i>Retinopathies NEC</i></b>		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	4	0
<b><i>Structural change, deposit and degeneration of eye NEC</i></b>		
Exophthalmos	1	0
<b><i>Visual colour distortions</i></b>		
Cyanopsia	1	0
Xanthopsia	1	0
<b><i>Visual disorders NEC</i></b>		
Diplopia	17	0
Halo vision	1	0
Metamorphopsia	3	0
Photopsia	15	0
Vision blurred	180	0
<b><i>Visual field disorders</i></b>		
Visual field defect	2	0
<b><i>Visual impairment and blindness (excl colour blindness)</i></b>		
Blindness	18	0
Blindness transient	4	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	31	0
<b>Eye disorders SOC TOTAL</b>	<b>780</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal pains</i>		
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	3	0
Colitis ulcerative	5	0
Crohn's disease	7	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teething	1	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	3	0
Hyperaesthesia teeth	4	0
Toothache	15	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	608	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	67	0
Epigastric discomfort	1	0
Eructation	8	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	7	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	36	0
Flatulence	21	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	191	0
Abdominal pain lower	16	0
Abdominal pain upper	435	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	15	0
Oesophageal pain	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	25	0
Gastrooesophageal reflux disease	22	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Food poisoning	1	0
Gastric disorder	1	0
Gastrointestinal disorder	1	0
Stomach mass	1	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Gastrointestinal inflammation	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Hyperchlorhydria	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	82	0
Anal incontinence	3	0
Breath odour	5	0
Dysphagia	20	0
Odynophagia	6	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	1	0
Frequent bowel movements	5	0
Irritable bowel syndrome	9	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	1	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	2	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival pain	9	0
Gingival swelling	5	0
Noninfective gingivitis	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	9	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoids	3	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	1	0
Rectal haemorrhage	12	0
<b><i>Malabsorption syndromes</i></b>		
Coeliac disease	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	1	0
Nausea	2505	0
Regurgitation	1	0
Retching	16	0
Vomiting	910	0
Vomiting projectile	5	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	1	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Haematemesis	3	0
Haematochezia	5	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	1	0
Dry mouth	58	0
Lip dry	4	0
Saliva altered	2	0
Salivary hypersecretion	6	0
<b>Oral soft tissue disorders NEC</b>		
Chapped lips	1	0
Cheilitis	2	0
Enlarged uvula	1	0
Lip blister	2	0
Lip disorder	1	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	4	0
Oral blood blister	2	0
<b>Oral soft tissue signs and symptoms</b>		
Coating in mouth	2	0
Hypoaesthesia oral	50	0
Lip discolouration	1	0
Lip pain	4	0
Lip pruritus	1	0
Oral discomfort	6	0
Oral mucosal eruption	1	0
Oral mucosal roughening	1	0
Oral pain	16	0
Oral pruritus	1	0
Paraesthesia oral	84	0
<b>Oral soft tissue swelling and oedema</b>		
Lip swelling	100	0
Mouth swelling	10	0
<b>Pancreatic disorders NEC</b>		
Pancreatic failure	1	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer haemorrhage	2	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland pain	1	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	3	0
Lip ulceration	3	0
Mouth ulceration	55	0
Stomatitis	3	0
<b>Tongue disorders</b>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Glossitis	4	0
Tongue disorder	5	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	19	0
Swollen tongue	48	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	3	0
Tongue discomfort	4	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	2	0
<b><i>Tooth missing</i></b>		
Tooth loss	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>5683</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Administration site reaction	1	0
Administration site warmth	1	0
Puncture site bruise	5	0
Puncture site pain	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	6	0
Application site joint erythema	1	0
Application site pain	2	0
Application site pruritus	10	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	2	0
<b><i>Asthenic conditions</i></b>		
Asthenia	319	0
Chronic fatigue syndrome	5	0
Fatigue	3308	0
Malaise	600	0
<b><i>Body temperature altered</i></b>		
Hypothermia	2	0
<b><i>Death and sudden death</i></b>		
Death	8	8
Sudden death	1	1
<b><i>Febrile disorders</i></b>		
Pyrexia	3639	1
<b><i>Feelings and sensations NEC</i></b>		
Chills	2125	0
Feeling abnormal	281	0
Feeling cold	168	0
Feeling drunk	11	0
Feeling hot	223	0
Feeling jittery	9	0
Feeling of body temperature change	66	0
Hangover	14	0
Hunger	15	0
Sensation of blood flow	1	0
Sensation of foreign body	5	0
Temperature intolerance	18	0
Thirst	61	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	20	0
Gait inability	7	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	12	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Crying	24	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Illness	327	0
Induration	7	0
Influenza like illness	417	0
Irritability postvaccinal	1	0
Local reaction	22	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1434	0
Screaming	4	0
Secretion discharge	2	0
Swelling	743	0
Swelling face	87	0
<b>Implant and catheter site reactions</b>		
Implant site warmth	3	0
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	103	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
<b>Infusion site reactions</b>		
Infusion site erythema	1	0
Infusion site mass	1	0
Infusion site pain	4	0
Infusion site pruritus	2	0
Infusion site urticaria	2	0
Infusion site warmth	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	5	0
Injection site bruising	11	0
Injection site discolouration	1	0
Injection site erythema	130	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	5	0
Injection site indentation	2	0
Injection site inflammation	10	0
Injection site irritation	3	0
Injection site joint erythema	4	0
Injection site joint pain	1	0
Injection site mass	140	0
Injection site oedema	2	0
Injection site pain	480	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	91	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site rash	165	0
Injection site reaction	15	0
Injection site swelling	67	0
Injection site urticaria	46	0
Injection site vesicles	1	0
Injection site warmth	69	0
<b>Interactions</b>		
Alcohol interaction	1	0
Drug interaction	2	0
<b>Mass conditions NEC</b>		
Cyst	5	0
Mass	18	0
Nodule	5	0
<b>Mucosal findings abnormal</b>		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
<b>Oedema NEC</b>		
Face oedema	3	0
Localised oedema	1	0
Oedema	6	0
Oedema peripheral	9	0
<b>Pain and discomfort NEC</b>		
Axillary pain	476	0
Chest discomfort	220	0
Chest pain	679	0
Discomfort	82	0
Facial pain	20	0
Inflammatory pain	2	0
Non-cardiac chest pain	2	0
Pain	1540	0
Tenderness	132	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	31	0
Adverse event	1	0
Adverse reaction	3	0
Drug ineffective	10	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	3	0
Therapeutic product effect decreased	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	2	0
<b>Ulcers NEC</b>		
Ulcer	4	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	5	0
Vaccination site bruising	15	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0



## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site eczema	1	0
Vaccination site erythema	243	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	16	0
Vaccination site inflammation	9	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	2	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	60	0
Vaccination site movement impairment	9	0
Vaccination site oedema	1	0
Vaccination site pain	250	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	57	0
Vaccination site rash	123	0
Vaccination site reaction	4	0
Vaccination site scar	1	0
Vaccination site swelling	145	0
Vaccination site urticaria	11	0
Vaccination site vesicles	1	0
Vaccination site warmth	106	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	6	0
<b>General disorders SOC TOTAL</b>	<b>19788</b>	<b>11</b>

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### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	0
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
Jaundice cholestatic	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic steatosis	1	0
Immune-mediated hepatitis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	215	0
Infusion related hypersensitivity reaction	12	0
Multiple allergies	2	0
Serum sickness	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	2	0
Allergy to vaccine	10	0
Drug hypersensitivity	8	0
Milk allergy	1	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	47	0
Anaphylactic shock	4	0
Anaphylactoid reaction	3	0
<i>Atopic disorders</i>		
Seasonal allergy	14	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	36	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
Sensitisation	3	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>387</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Appendicitis	4	0
Diverticulitis	2	0
Gastroenteritis	2	0
<i><b>Bacterial infections NEC</b></i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	56	0
Folliculitis	1	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	3	0
<i><b>Breast infections</b></i>		
Breast abscess	1	0
Mastitis	4	0
<i><b>Candida infections</b></i>		
Candida infection	4	0
Oral candidiasis	1	0
Vulvovaginal candidiasis	7	0
<i><b>Cardiac infections</b></i>		
Endocarditis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Central nervous system infection	1	0
Meningitis	2	0
<i><b>Coronavirus infections</b></i>		
COVID-19	82	0
COVID-19 pneumonia	4	0
Suspected COVID-19	2	0
<i><b>Coxiella infections</b></i>		
Q fever	4	0
<i><b>Cytomegaloviral infections</b></i>		
Cytomegalovirus infection	1	0
Cytomegalovirus infection reactivation	2	0
<i><b>Dental and oral soft tissue infections</b></i>		
Gingivitis	2	0
Tooth abscess	1	0
Tooth infection	1	0
<i><b>Ear infections</b></i>		
Ear infection	3	0
Labyrinthitis	4	0
Otitis externa	1	0
<i><b>Ectoparasitic infestations</b></i>		
Acarodermatitis	1	0
<i><b>Enteroviral infections NEC</b></i>		
Hand-foot-and-mouth disease	1	0
<i><b>Epstein-Barr viral infections</b></i>		
Infectious mononucleosis	2	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	9	0
Eye infection	2	0
Eyelid boil	1	0
Hordeolum	2	0
<i><b>Female reproductive tract infections</b></i>		

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Vaginal infection	1	0
<b>Flaviviral infections</b>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<b>Fungal infections NEC</b>		
Fungal infection	3	0
Fungal skin infection	2	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
<b>Fusobacterium infections</b>		
Necrotising ulcerative gingivostomatitis	1	0
<b>Herpes viral infections</b>		
Eczema herpeticum	2	0
Genital herpes	10	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes zoster	51	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	50	0
Varicella	1	0
<b>Infections NEC</b>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	63	0
Injection site infection	1	0
Localised infection	16	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	4	0
Vestibulitis	1	0
Wound infection	1	0
<b>Infectious disorders carrier</b>		
SARS-CoV-2 carrier	2	0
<b>Infectious transmissions</b>		
Secondary transmission	2	0
<b>Influenza viral infections</b>		
Influenza	307	0
<b>Lower respiratory tract and lung infections</b>		
Atypical pneumonia	1	0
Bronchitis	3	0
Lower respiratory tract infection	29	1
Pneumonia	9	1
<b>Male reproductive tract infections</b>		
Epididymitis	1	0
Orchitis	1	0
<b>Mumps viral infections</b>		
Mumps	1	0
<b>Nematode infections</b>		
Enterobiasis	1	0
<b>Rabies viral infections</b>		
Rabies	1	1
<b>Rubella viral infections</b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Rubella	2	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Sepsis	1	0
Septic shock	1	0
Urosepsis	1	0
<b>Skin structures and soft tissue infections</b>		
Acne pustular	1	0
Eczema infected	1	0
Impetigo	2	0
Pustule	9	0
Pyoderma	1	0
Rash pustular	2	0
Skin infection	9	0
Vaccination site pustule	1	0
<b>Staphylococcal infections</b>		
Furuncle	5	0
<b>Tinea infections</b>		
Body tinea	3	0
Tinea infection	1	0
<b>Tuberculous infections</b>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
<b>Upper respiratory tract infections</b>		
Laryngitis	1	0
Nasopharyngitis	188	0
Peritonsillar abscess	1	0
Pharyngitis	3	0
Rhinitis	3	0
Sinusitis	13	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
<b>Urinary tract infections</b>		
Cystitis	6	0
Kidney infection	2	0
Urinary tract infection	20	0
<b>Vascular infections</b>		
Lymphangitis	2	0
<b>Viral infections NEC</b>		
Conjunctivitis viral	1	0
Gastroenteritis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	3	0
Sweating fever	33	0
Vestibular neuronitis	1	0
Viral infection	3	0
Viral labyrinthitis	1	0
Viral pharyngitis	3	0
Viral rash	6	0
<b>Infections SOC TOTAL</b>	<b>1144</b>	<b>3</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Oral contusion	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	1	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Anaesthetic complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotrauma	1	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	1	0
<b><i>Cerebral injuries NEC</i></b>		
Concussion	6	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	8	0
<b><i>Cranial nerve injuries</i></b>		
Optic nerve injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	16	0
Foetal exposure during pregnancy	7	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	372	0
Maternal exposure during pregnancy	182	0
Maternal exposure timing unspecified	1	0
<b><i>Exposures to agents or circumstances NEC</i></b>		
Exposure to SARS-CoV-2	2	0
<b><i>Fractures and dislocations NEC</i></b>		
Joint dislocation	1	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat oedema	4	0
Heat stroke	7	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	4	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	6	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	3	0
Muscle injury	1	0
Muscle strain	2	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	12	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Procedural dizziness	3	0
<b><i>Non-occupational environmental exposures</i></b>		
Exposure to extreme temperature	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Arthropod bite	3	0
Bite	1	0
Electric shock	5	0
Fall	22	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Inflammation of wound	1	0
Injury	3	0
Nervous system injury	1	0
Wound complication	4	0
Wound haemorrhage	1	0
<b>Non-site specific procedural complications</b>		
Injection related reaction	8	0
Post procedural erythema	1	0
Procedural pain	1	0
<b>Occupational exposures</b>		
Occupational exposure to toxic agent	1	0
<b>Off label uses</b>		
Off label use	4	0
<b>Overdoses NEC</b>		
Overdose	7	0
<b>Peripheral nerve injuries</b>		
Sciatic nerve injury	1	0
<b>Poisoning and toxicity</b>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<b>Product administration errors and issues</b>		
Accidental overdose	6	0
Expired product administered	20	0
Inappropriate schedule of product administration	19	0
Incorrect dose administered	2	0
Incorrect route of product administration	2	0
Poor quality product administered	1	0
Product administered at inappropriate site	3	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	1	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	1	0
<b>Radiation injuries</b>		
Sunburn	12	0
<b>Site specific injuries NEC</b>		
Back injury	1	0
Head injury	5	0
Limb injury	21	0
<b>Skin injuries NEC</b>		
Contusion	201	0
Scar	8	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<b>Spinal cord injuries NEC</b>		
Spinal cord injury cervical	1	0
<b>Stoma complications</b>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<b>Thermal burns</b>		
Burn oesophageal	1	0



# Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Burns third degree	4	0
Cold burn	1	0
Thermal burn	11	0
Thermal burns of eye	1	0
<b><i>Thoracic cage fractures and dislocations</i></b>		
Sternal fracture	1	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	7	0
<b>Injuries SOC TOTAL</b>	<b>1057</b>	<b>0</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b>Adrenal medulla tests</b>		
Norepinephrine increased	2	0
<b>Bacteria identification and serology (excl mycobacteria)</b>		
Campylobacter test positive	1	0
<b>Blood counts NEC</b>		
Full blood count abnormal	1	0
<b>Blood gas and acid base analyses</b>		
Oxygen consumption decreased	1	0
Oxygen saturation	1	0
Oxygen saturation decreased	8	0
<b>Carbohydrate tolerance analyses (incl diabetes)</b>		
Blood glucose	1	0
Blood glucose decreased	1	0
Blood glucose increased	3	0
<b>Cardiac auscultatory investigations</b>		
Cardiac murmur	1	0
Heart sounds	3	0
<b>Cardiac function diagnostic procedures</b>		
Ejection fraction decreased	1	0
<b>Central nervous system imaging procedures</b>		
Computerised tomogram head	1	0
<b>Cholesterol analyses</b>		
Low density lipoprotein increased	1	0
<b>Coagulation and bleeding analyses</b>		
Bleeding time abnormal	1	0
Fibrin D dimer increased	1	0
<b>ECG investigations</b>		
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	1	0
Electrocardiogram change	1	0
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	8	0
<b>Fertility analyses</b>		
Semen analysis abnormal	1	0
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<b>Fungus identification and serology</b>		
Fungal test	1	0
<b>Gastrointestinal and abdominal imaging procedures</b>		
X-ray with contrast upper gastrointestinal tract	1	0
<b>Heart rate and pulse investigations</b>		
Heart rate	126	0
Heart rate abnormal	10	0
Heart rate decreased	8	0
Heart rate increased	185	0
Heart rate irregular	36	0
Heart rate variability decreased	1	0
<b>Investigations NEC</b>		

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood test abnormal	3	0
<b>Liver function analyses</b>		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	2	0
Bile output	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	6	0
Liver function test increased	1	0
<b>Mineral and electrolyte analyses</b>		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
<b>Musculoskeletal and soft tissue imaging procedures</b>		
Bone scan	1	0
<b>Musculoskeletal and soft tissue tests NEC</b>		
Tender joint count	1	0
<b>Neurologic diagnostic procedures</b>		
Coma scale abnormal	2	0
Sensory level	1	0
<b>Ophthalmic function diagnostic procedures</b>		
Visual tracking test abnormal	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature	52	0
Body temperature abnormal	3	0
Body temperature decreased	3	0
Body temperature fluctuation	13	0
Body temperature increased	54	0
Grip strength	1	0
Grip strength decreased	1	0
Head lag	1	0
Lymph node palpable	2	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	3	0
Respiratory rate decreased	4	0
Respiratory rate increased	7	0
Skin temperature	11	0
Temperature difference of extremities	1	0
Weight decreased	14	0
Weight increased	6	0
<b>Pituitary analyses anterior</b>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	1	0
<b>Platelet analyses</b>		
Platelet count decreased	7	0
<b>Protein analyses NEC</b>		
C-reactive protein increased	5	0
<b>Red blood cell analyses</b>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
<b>Renal function analyses</b>		
Blood creatinine increased	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Reproductive hormone analyses</i></b>		
Pregnancy test	1	0
<b><i>Reproductive organ and breast histopathology procedures</i></b>		
Smear cervix	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume increased	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	3	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	4	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood lactate dehydrogenase increased	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine present	9	0
Protein urine	1	0
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output	3	0
Urine output decreased	1	0
<b><i>Urinary tract imaging procedures</i></b>		
Bladder scan	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	13	0
Blood pressure measurement	3	0
<b><i>Virus identification and serology</i></b>		
Coronavirus test	4	0
Influenza A virus test	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	4	0
<b><i>Vitamin analyses</i></b>		
Blood folate decreased	1	0
<b><i>White blood cell analyses</i></b>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>718</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	2	0
Decreased appetite	212	0
Food craving	2	0
Food refusal	2	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	7	0
Salt craving	1	0
<i><b>Copper metabolism disorders</b></i>		
Copper deficiency	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	2	0
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	2	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	12	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	1	0
Food intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	2	0
Abnormal weight gain	5	0
Feeding disorder	31	0
Food aversion	4	0
Neonatal insufficient breast milk syndrome	3	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	5	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	7	0
<i><b>Potassium imbalance</b></i>		
Hypokalaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	54	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	8	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Folate deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>381</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	21	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	5	0
Autoimmune arthritis	1	0
<i><b>Bone disorders NEC</b></i>		
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	44	0
Bone swelling	1	0
Pain in jaw	50	0
Spinal pain	10	0
<i><b>Bursal disorders</b></i>		
Bursitis	9	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	13	0
<i><b>Connective tissue disorders NEC</b></i>		
Polymyalgia rheumatica	1	0
Reynold's syndrome	1	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	2	0
<i><b>Joint related disorders NEC</b></i>		
Joint lock	5	0
Periarthritis	22	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	1257	0
Joint noise	3	0
Joint stiffness	40	0
Joint swelling	36	0
Joint vibration	1	0
Joint warmth	3	0
<i><b>Lupus erythematosus (incl subtypes)</b></i>		
Lupus-like syndrome	1	0
<i><b>Muscle infections and inflammations</b></i>		
Myositis	6	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	13	0
Myalgia	1779	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle fatigue	53	0
Muscle haemorrhage	1	0
Muscle spasms	296	0
Muscle swelling	9	0
Muscle tightness	19	0
Muscle twitching	54	0
Myosclerosis	1	0

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### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	2	0
Nuchal rigidity	4	0
Trismus	4	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	115	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Growth retardation	1	0
Mastication disorder	2	0
Mobility decreased	8	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	264	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	2	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Dupuytren's contracture	1	0
Fasciitis	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	412	0
Flank pain	9	0
Limb discomfort	238	0
Musculoskeletal chest pain	25	0
Musculoskeletal discomfort	9	0
Musculoskeletal pain	12	0
Neck pain	217	0
Pain in extremity	2320	0
Sacral pain	1	0
<b><i>Myopathies</i></b>		
Rhabdomyolysis	1	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	4	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	1	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	5	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	28	0
Groin pain	14	0
Neck mass	6	0
Purple glove syndrome	1	0
Soft tissue swelling	1	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	2	0
Arthritis reactive	6	0
Axial spondyloarthritis	1	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	4	0
<b><i>Tendon disorders</i></b>		
Tendon pain	2	0
Trigger finger	2	0
<b><i>Trunk deformities</i></b>		

# Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b> Muscle & tissue disorders cont'd		
Shoulder deformity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>7497</b>	<b>0</b>



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Report Run Date: 02-Dec-2021

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>B-cell lymphomas NEC</b></i>		
B-cell lymphoma stage III	1	0
<i><b>Breast and nipple neoplasms benign</b></i>		
Benign breast neoplasm	1	0
<i><b>Breast and nipple neoplasms malignant</b></i>		
Breast cancer	3	0
<i><b>Leukaemias NEC</b></i>		
Leukaemia	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	5	0
<i><b>Mediastinal neoplasms malignancy unspecified NEC</b></i>		
Good syndrome	1	0
<i><b>Metastases to specified sites</b></i>		
Metastases to lymph nodes	1	0
<i><b>Metastases to unknown and unspecified sites</b></i>		
Metastasis	1	0
<i><b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b></i>		
Tonsil cancer	2	0
<i><b>Skin neoplasms benign</b></i>		
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	3	0
<i><b>Small intestinal neoplasms malignant</b></i>		
Small intestine adenocarcinoma	1	0
<i><b>Soft tissue neoplasms benign NEC</b></i>		
Lipoma	1	0
<i><b>Thyroid neoplasms malignant</b></i>		
Thyroid cancer	1	0
<i><b>Uterine neoplasms benign</b></i>		
Uterine leiomyoma	2	0
<b>Neoplasms SOC TOTAL</b>	<b>29</b>	<b>0</b>

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Report Run Date: 02-Dec-2021

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	7	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	2	1
Cerebral infarction	1	0
Cerebrovascular accident	13	1
Haemorrhage intracranial	1	0
Intracranial haematoma	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	2	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	41	0
Coordination abnormal	2	0
Dysstasia	4	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	9	0
Lethargy	284	0
Loss of consciousness	151	0
Somnolence	157	0
Stupor	1	0
Syncope	690	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	2	0
Dyskinesia	6	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	3	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	7	0
Movement disorder	8	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Psychomotor hyperactivity	1	0
<b>Dystonias</b>		
Dystonia	1	0
<b>Eye movement disorders</b>		
IVth nerve paresis	1	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	45	0
Facial paralysis	26	0
Facial paresis	4	0
Facial spasm	4	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	2	0
<b>Glossopharyngeal nerve disorders</b>		
Glossopharyngeal neuralgia	1	0
<b>Headaches NEC</b>		
Cluster headache	35	0
Cold-stimulus headache	6	0
Drug withdrawal headache	2	0
Headache	4209	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	49	0
Tension headache	87	0
Thunderclap headache	1	0
Vascular headache	2	0
<b>Increased intracranial pressure disorders</b>		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	3	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	4	0
<b>Memory loss (excl dementia)</b>		
Amnesia	24	0
Memory impairment	19	0
Transient global amnesia	1	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	12	0
Disturbance in attention	51	0
Mental impairment	6	0
<b>Migraine headaches</b>		
Hemiplegic migraine	3	0
Migraine	440	0
Migraine with aura	31	0
Migraine without aura	2	0
Retinal migraine	3	0
Typical aura without headache	1	0
Vestibular migraine	2	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Multiple sclerosis	1	0
<b>Muscle tone abnormal</b>		
Hypotonia	4	0
Stiff leg syndrome	2	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	2	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	13	0
Narcolepsy	1	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	2	0
Psychomotor skills impaired	1	0
<b>Neurologic visual problems NEC</b>		
Tunnel vision	8	0
<b>Neurological signs and symptoms NEC</b>		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	1937	0
Dizziness exertional	5	0
Dizziness postural	105	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	39	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	1	0
Presyncope	167	0
Unresponsive to stimuli	10	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	2	0
Muscle spasticity	3	0
<b>Olfactory nerve disorders</b>		
Anosmia	23	0
Parosmia	21	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	2	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	2	0
Burning sensation	66	0
Formication	3	0
Hemianaesthesia	2	0
Hyperaesthesia	33	0
Hypoaesthesia	383	0
Paraesthesia	534	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	4	0
Hemiplegia	5	0
Monoparesis	11	0
Monoplegia	16	0
Paralysis	15	0
Paresis	2	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	2	0
Reduced facial expression	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<b><i>Peripheral neuropathies NEC</i></b>		
Autoimmune neuropathy	1	0
Neuralgic amyotrophy	1	0
Neuritis	1	0
Neuropathy peripheral	5	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	10	0
Febrile convulsion	3	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	114	0
Seizure anoxic	1	0
Status epilepticus	27	0
Tonic clonic movements	3	0
Tonic convulsion	2	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	47	0
Allodynia	1	0
Aura	1	0
Complex regional pain syndrome	1	0
Dysgeusia	131	0
Electric shock sensation	6	0
Hypogeusia	1	0
Neuralgia	56	0
Post herpetic neuralgia	2	0
Restless legs syndrome	26	0
Sensory disturbance	8	0
Sensory loss	16	0
Taste disorder	29	0
Vibratory sense increased	1	0
<b><i>Sleep disturbances NEC</i></b>		
Sleep deficit	3	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	20	0
Incoherent	7	0
Slow speech	4	0
Speech disorder	10	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Radiculopathy	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	7	0
<b><i>Tremor (excl congenital)</i></b>		
Head titubation	1	0
Tremor	317	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>10811</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	39	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	3	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	3	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>64</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device expulsion	1	0
Device leakage	1	0
<b><i>Device malfunction events NEC</i></b>		
Thrombosis in device	1	0
<b><i>Manufacturing materials issues</i></b>		
Manufacturing materials issue	1	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination physical	8	0
<b><i>Product physical issues</i></b>		
Product after taste	1	0
Product taste abnormal	1	0
<b><i>Product quality issues NEC</i></b>		
Product impurity	1	0
Product quality issue	1	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	2	0
<b>null SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	3	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	2	0
Flat affect	3	0
Inappropriate affect	1	0
<b><i>Anxiety disorders NEC</i></b>		
Separation anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	16	0
Anxiety	168	0
Nervousness	26	0
Stress	14	0
Tension	7	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	3	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Disinhibition	1	0
Paranoia	5	0
Personality change	1	0
Social avoidant behaviour	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Distractibility	1	0
Mental fatigue	30	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	109	0
Disorientation	43	0
<b><i>Deliria</i></b>		
Delirium	24	0
<b><i>Delusional disorders</i></b>		
Alice in wonderland syndrome	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	1	0
<b><i>Depressive disorders</i></b>		
Depression	53	0
Depression suicidal	4	0
Major depression	1	0
Mixed anxiety and depressive disorder	1	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	2	0
Dissociation	10	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	2	0
Insomnia	212	0
Middle insomnia	9	0
Terminal insomnia	10	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	44	0
<b><i>Eating disorders NEC</i></b>		
Binge eating	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Anger	8	0
Emotional disorder	14	0
Emotional distress	8	0
Euphoric mood	8	0
Irritability	37	0
Mood altered	10	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	2	0
Fear of death	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	12	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	61	0
Hallucination, auditory	3	0
Hallucination, tactile	1	0
Hallucination, visual	1	0
Somatic hallucination	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	34	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	4	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	65	0
Feeling of despair	3	0
Tearfulness	2	0
<b><i>Mood alterations with manic symptoms</i></b>		
Mania	4	0
<b><i>Mood disorders NEC</i></b>		
Apathy	6	0
Listless	4	0
<b><i>Narcolepsy and associated conditions</i></b>		
Hypnagogic hallucination	1	0
<b><i>Orgasmic disorders and disturbances</i></b>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<b><i>Panic attacks and disorders</i></b>		
Limited symptom panic attack	1	0
Panic attack	38	0
Panic reaction	7	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	21	0
Nightmare	27	0
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	3	0
Somnambulism	1	0
<b><i>Perception disturbances NEC</i></b>		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	8	0
<b><i>Psychiatric symptoms NEC</i></b>		
Psychiatric symptom	1	0
Psychological trauma	1	0
<b><i>Psychotic disorder NEC</i></b>		
Acute psychosis	1	0
Psychotic disorder	1	0
<b><i>Sexual desire disorders</i></b>		
Libido decreased	4	0
Libido increased	1	0
Loss of libido	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	33	0
<b><i>Somatic symptom disorders</i></b>		
Conversion disorder	4	0
Habit cough	4	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	1	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	3	0
Lack of spontaneous speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	2	0
Head banging	1	0
<b><i>Substance related and addictive disorders</i></b>		
Alcoholism	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	12	0
Suicide attempt	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>1310</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder irritation	1	0
Bladder pain	4	0
Dysuria	6	0
Incontinence	7	0
Micturition urgency	4	0
Pollakiuria	22	0
Urethral pain	1	0
Urinary incontinence	8	0
Urinary retention	2	0
Urinary straining	1	0
Urine flow decreased	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	2	0
<i><b>Genitourinary tract infections and inflammations NEC</b></i>		
Urinary tract inflammation	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
IgA nephropathy	2	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	4	0
Oliguria	1	0
Renal impairment	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	10	0
Haematuria	3	0
Urine abnormality	4	0
Urine odour abnormal	3	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	5	0
Renal pain	49	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>143</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	3	0
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	3	0
Breast mass	10	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	2	0
Breast discomfort	2	0
Breast oedema	1	0
Breast pain	77	0
Breast swelling	9	0
Breast tenderness	10	0
Nipple pain	1	0
Nipple swelling	2	0
<i><b>Cervix disorders NEC</b></i>		
Ectropion of cervix	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	11	0
Nocturnal emission	1	0
Organic erectile dysfunction	8	0
Painful ejaculation	1	0
<i><b>Gender disorders</b></i>		
Feminisation acquired	1	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	1	0
Lactation puerperal increased	2	0
Suppressed lactation	7	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	6	0
Premature menopause	3	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	10	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	314	0
Intermenstrual bleeding	153	0
Menstrual discomfort	2	0
Menstrual disorder	264	0
Menstruation irregular	429	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	14	0
Premenstrual syndrome	13	0
Withdrawal bleed	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	63	0
Hypomenorrhoea	85	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Menstruation delayed	555	0
Oligomenorrhoea	20	0
<b>Menstruation with increased bleeding</b>		
Heavy menstrual bleeding	718	0
Menometrorrhagia	6	0
Polymenorrhoea	102	0
<b>Ovarian and fallopian tube cysts and neoplasms</b>		
Ovarian cyst	7	0
Polycystic ovaries	5	0
<b>Ovarian and fallopian tube disorders NEC</b>		
Ovulation pain	15	0
Premature ovulation	1	0
<b>Pelvis and broad ligament disorders NEC</b>		
Adnexa uteri pain	11	0
Pelvic haemorrhage	2	0
<b>Penile disorders NEC (excl erection and ejaculation)</b>		
Penile pain	1	0
Penis disorder	3	0
<b>Prostate and seminal vesicles infections and inflammations</b>		
Prostatitis	2	0
<b>Prostatic signs, symptoms and disorders NEC</b>		
Prostatic pain	1	0
<b>Reproductive tract disorders NEC (excl neoplasms)</b>		
Genital haemorrhage	2	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<b>Reproductive tract signs and symptoms NEC</b>		
Genital odour	1	0
Genital pain	1	0
Pelvic pain	16	0
<b>Scrotal disorders NEC</b>		
Scrotal pain	4	0
Varicocele	1	0
<b>Sexual function and fertility disorders NEC</b>		
Infertility	3	0
Sexual dysfunction	1	0
<b>Spermatogenesis and semen disorders</b>		
Haemospermia	1	0
<b>Testicular and epididymal disorders NEC</b>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	11	0
Testicular swelling	4	0
<b>Uterine disorders NEC</b>		
Adenomyosis	1	0
Endometriosis	10	0
Uterine haemorrhage	8	0
Uterine pain	4	0
<b>Uterine tone disorders</b>		
Uterine spasm	12	0
<b>Vulvovaginal cysts and neoplasms</b>		
Vaginal cyst	1	0
Vulva cyst	1	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	208	0
Vaginal ulceration	1	0
Vulval haemorrhage	6	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Labia enlarged	1	0
Vaginal discharge	12	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>3296</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	1	0
Dyspnoea	623	0
Dyspnoea exertional	4	0
Hyperventilation	4	0
Hypopnoea	15	0
Hypoventilation	1	0
Irregular breathing	2	0
Respiration abnormal	11	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	2	0
Tachypnoea	4	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	37	0
Asthma exercise induced	1	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	1	0
Childhood asthma	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	62	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	2	0
Cough	288	0
Haemoptysis	1	0
Productive cough	19	0
Sputum discoloured	2	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonitis	2	0
Pulmonary sarcoidosis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	14	0
Pulmonary haemorrhage	1	0
Pulmonary pain	12	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	41	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	107	0
Nasal dryness	2	0
Nasal oedema	1	0
Nasal pruritus	3	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	1	0
Sinus congestion	10	0
Sinus disorder	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Parenchymal lung disorders NEC</i></b>		
Interstitial lung disease	2	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	4	0
Pharyngeal swelling	42	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	8	0
<b><i>Pleural infections and inflammations</i></b>		
Pleurisy	5	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	3	0
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary hypertension	1	0
<b><i>Pulmonary oedemas</i></b>		
Pulmonary congestion	2	0
Pulmonary oedema	4	0
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary embolism	20	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Respiratory failure	1	0
<b><i>Respiratory signs and symptoms NEC</i></b>		
Diaphragmalgia	2	0
Respiratory symptom	2	0
<b><i>Respiratory tract disorders NEC</i></b>		
Allergic respiratory disease	1	0
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	6	0
Catarrh	1	0
Choking	3	0
Dry throat	17	0
Dysphonia	10	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	4	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	311	0
Paranasal sinus discomfort	5	0
Rhinalgia	2	0
Rhinorrhoea	87	0
Sinus pain	37	0
Sneezing	26	0
Throat irritation	21	0
Throat tightness	37	0
Upper-airway cough syndrome	1	0
Yawning	5	0
<b>Respiratory disorders SOC TOTAL</b>	<b>1970</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	28	0
<b><i>Alopecias</i></b>		
Alopecia	38	0
Alopecia areata	6	0
Alopecia totalis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	27	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	178	0
Hidradenitis	1	0
Hyperhidrosis	574	0
Miliaria	49	0
Night sweats	133	0
<b><i>Bullous conditions</i></b>		
Blister	42	0
Blister rupture	1	0
Blood blister	1	0
Dermatitis bullous	1	0
Erythema multiforme	11	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	67	0
Pain of skin	65	0
Papule	20	0
Scab	5	0
Scar pain	2	0
Sensitive skin	88	0
Skin burning sensation	43	0
Skin discolouration	26	0
Skin induration	7	0
Skin lesion	22	0
Skin odour abnormal	1	0
Skin reaction	86	0
Skin sensitisation	10	0
Skin swelling	14	0
Skin tightness	4	0
Skin warm	173	0
Yellow skin	2	0
<b><i>Dermatitis and eczema</i></b>		
Autoimmune dermatitis	1	0
Dermatitis	22	0
Dermatitis allergic	80	0
Dermatitis atopic	11	0
Dermatitis contact	6	0
Dyshidrotic eczema	9	0
Eczema	45	0
Eczema nummular	2	0
Neurodermatitis	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin irritation	19	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	2	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	827	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	9	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<b><i>Hypopigmentation disorders</i></b>		
Vitiligo	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Onychoclasia	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	3	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	2	0
Pityriasis rosea	8	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	15	0
<b><i>Pilar disorders NEC</i></b>		
Piloerection	9	0
Trichodynia	1	0
<b><i>Pruritus NEC</i></b>		
Itching scar	3	0
Pruritus	1765	0
<b><i>Psoriatic conditions</i></b>		
Guttate psoriasis	1	0
Psoriasis	17	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	14	0
Purpura	8	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	1	0
Rash	2025	0
Rash erythematous	803	0
Rash macular	134	0
Rash maculo-papular	2	0
Rash morbilliform	5	0
Rash papular	137	0
Rash pruritic	446	0
Rash vesicular	5	0
<b><i>Rosaceas</i></b>		
Rosacea	2	0
<b><i>Scaly conditions</i></b>		
Pityriasis	2	0
<b><i>Sebaceous gland disorders</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Seborrhoea	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	3	0
Skin mass	6	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin erosion	2	0
Skin ulcer	2	0
<b>Skin cysts and polyps</b>		
Dermal cyst	7	0
<b>Skin dystrophies</b>		
Keloid scar	1	0
Skin wrinkling	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	2	0
<b>Skin injuries and mechanical dermatoses</b>		
Needle track marks	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	3	0
Vasculitic rash	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	3	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	312	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	2	0
<b>Skin disorders SOC TOTAL</b>	<b>8536</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menarche	1	0
Menopause	5	0
<i>Disability issues</i>		
Bedridden	3	0
Immobile	3	0
Impaired driving ability	2	0
Loss of personal independence in daily activities	1	0
Sight disability	2	0
<i>Employment issues</i>		
Retirement	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	5	0
<i>Social issues NEC</i>		
Social problem	1	0
<b>Social circumstances SOC TOTAL</b>	<b>26</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	17	0
Immunisation	27	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	4	0
<i>Therapeutic procedures NEC</i>		
Bed rest	3	0
Botulinum toxin injection	1	0
Hospitalisation	3	0
Injection	21	0
Interchange of vaccine products	2	0
Polypectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>90</b>	<b>0</b>

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Accelerated and malignant hypertension</b></i>		
Hypertensive urgency	1	0
<i><b>Arterial infections and inflammations</b></i>		
Giant cell arteritis	1	0
<i><b>Blood pressure disorders NEC</b></i>		
Blood pressure fluctuation	1	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	1	0
Neurogenic shock	1	0
Shock	2	0
<i><b>Haemorrhages NEC</b></i>		
Bloody discharge	2	0
Haematoma	4	0
Haemorrhage	162	0
<i><b>Lymphangiopathies</b></i>		
Lymphocele	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	11	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Embolism	1	0
Embolism venous	1	0
Thrombosis	30	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Vascular pain	5	0
Vasodilatation	2	0
Vein rupture	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	3	0
Deep vein thrombosis	13	0
Superficial vein thrombosis	1	0
Thrombophlebitis	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	6	0
Flushing	34	0
Hot flush	183	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	51	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	2	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	66	0
<i><b>Varicose veins NEC</b></i>		
Spider vein	1	0
Varicose vein	3	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	61	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Prehypertension	1	0
White coat hypertension	1	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	1	0
Hypotension	65	0
Orthostatic hypotension	5	0
<b><i>Vasculitides NEC</i></b>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>734</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>67504</b>	<b>18</b>
<b>TOTAL REPORTS</b>	<b>20520</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>18</b>